

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trad mark Offic**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

VB

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/461,774 12/15/99 CHAN

L 1781-180P

HM22/0117  
BIRCH STEWART KOLASCH & BIRCH LLP  
PO BOX 747  
FALLS CHURCH VA 22040-0747

EXAMINER

SWARTZ, R

ART UNIT

PAPER NUMBER

1645

9

DATE MAILED:

01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trad marks****BEST AVAILABLE COPY**

|                              |  |                                   |
|------------------------------|--|-----------------------------------|
| <b>Office Action Summary</b> | Application No.<br>09/461,774              | App. List(s)<br><b>Chan et al</b> |
|                              | Examiner<br><b>Rodney P. Swartz, Ph.D.</b> | Group Art Unit<br><b>1645</b>     |



Responsive to communication(s) filed on 2 November 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) 10-26 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-9 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

**DETAILED ACTION**

1. Applicants' Response to Restriction/Election Requirement, received 2 November 2000, paper #8, is acknowledged. Applicants elect, with traverse, Invention I, claims 1-9, drawn to polypeptides, classified in class 424, subclass 248.1. Applicants elect, with traverse, species *Mycobacterium tuberculosis*, molecular weight of 55-65kDa, and sequence <400>2.

Applicants did not put forth grounds of traversal, therefore, the requirement is still deemed proper and is made FINAL

Claims 10-26 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-9 are pending. Claims 10-26 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention.

3. Currently, claims 1-9 are under consideration.

**Specification**

4. The disclosure is objected to because of the following informalities:  
a) throughout the specification and claims it appears that the sequence identifiers are labeled <400> instead of the standard SEQ ID NO.: For example, <400>2 should be SEQ ID NO:2,

Appropriate correction is required.

**Claim Rejections - 35 USC § 112**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**6.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**7.** Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to isolated polypeptides which is “substantially” not immunointeractive with sera. The specification does not define the metes and bounds of the term “substantially”, therefore it is indefinite.

**8.** Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amino acid sequences are identified as <400>2, <400>4, etc. It is unclear if such designation is supposed to be the standard designation of SEQ ID NO:2, SEQ ID NO:4, etc.

**Claim Rejections - 35 USC § 102**

**9.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1645

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Thybo et al (*Tubercle and Lung Disease*, 76:149-155, 1995).

The claims are directed to an isolated polypeptide from *M. tuberculosis* which reacts with sera from subjects exposed to a *M. tuberculosis*, but which does not react with sera from subjects not prior exposed to *M. tuberculosis*.

Thybo et al teach serodiagnosis of tuberculosis using *M. tuberculosis* polypeptides of 38 kDa and 17kDa (Abstract; section **ELISA**, page 151). The polypeptides react with sera from humans who were prior exposed to *M. tuberculosis* (pulmonary TB patients) but the polypeptides do not react with sera from humans not exposed to *M. tuberculosis* (controls) (Tables 1-4; section **Results**, pages 151-152).

### Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

*Rodney P. Swart*  
RODNEY P. SWART, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

January 16, 2001